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COMBINED TRANSMITTAL OF APPEAL BRIEF TO THE BOARD OF PATENT APPEALS AND INTERFERENCES & PETITION FOR EXTENSION OF TIME UNDER 37 C.F.R. 1.136(a) (Large Entity)	Docket No. PU9843

In Re Application Of: **Tor Regberg, et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
09/869,023	August 6, 2001	Roy R. Teller	22840	1654	6811

Invention:

Removal/Purification of Serum Albumins

COMMISSIONER FOR PATENTS:

This is a combined Transmittal of Appeal Brief to the Board of Patent Appeals and Interferences and petition under the provisions of 37 CFR 1.136(a) to extend the period for filing an Appeal Brief.

Applicant(s) hereby request(s) an extension of time of (check desired time period):

☒ One month ☐ Two months ☐ Three months ☐ Four months ☐ Five months

from: **June 28, 2004** (*Date*) until: **July 28, 2004** (*Date*)

The fee for the Appeal Brief and Extension of Time has been calculated as shown below:

Fee for Appeal Brief:	$330.00
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TOTAL FEE FOR APPEAL BRIEF AND EXTENSION OF TIME:	**$440.00**

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TO THE COMMISSIONER FOR PATENTS:

This combined Transmittal of Appeal Brief to the Board of Patent Appeals and Interferences and petition for extension of time under 37 CFR 1.136(a) is respectfully submitted by the undersigned:

Signature

Dated: **July 26, 2004**

Royal N. Ronning, Jr.
Amersham Biosciences Corp
Patent Department
800 Centennial Avenue
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(732) 457-8423
Reg. No.: 32,529

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Melissa Leck

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	09/869,023	Confirmation No.: 6811
Applicant	:	Tor Regberg, et al.	
Filed	:	August 6, 2001	
TC/A.U.	:	1654	
Examiner	:	Roy R. Teller	
Docket No.	:	PU9843	
Customer No.	:	22840	

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Alexandria, Virginia 22313-1450

July 26, 2004

APPEAL BRIEF

Sir:

Appellants submit this Appeal Brief in triplicate, appealing from the January 28, 2004, rejection of the Primary Examiner, finally rejecting claims 1–8 in the captioned application. The Notice of Appeal was filed on April 28, 2004. Appellants are also submitting, concurrently herewith, a petition to extend the period to file the Appeal Brief one month from June 28, 2004, up to and including July 28, 2004.

Real Party in Interest

Amersham Biosciences AB, formerly known as Amersham Pharmacia Biotech AB, the assignee and owner of the captioned application, is the real party in interest to this appeal.

Related Appeals and Interferences

There are no other appeals or interferences related to the instant appeal.

Status of Claims

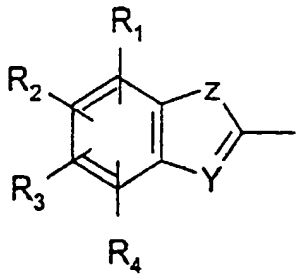
Claims 9 and 10 have been withdrawn from consideration. The claims currently under examination, namely claims 1-8, are attached hereto.

Status of Amendments

There are no outstanding amendments with regard to the captioned application.

Summary of Invention

The instant invention relates to a method for selectively enriching/removing a serum albumin from a mixture of other compounds by contacting said mixture with a ligand which has a affinity for enabling and binding of the serum albumin (X) attached by a spacer (B) to a base matrix (M) insoluble in the acqueous media used, the matrix with the attached ligand being represented by M-B-X, were in X it is selected among serum albumin-binding structures having the following formula:



in which

a) the free valence bind to the spacer B;

b) R_{1-4} are selected from hydrogen, electron-withdrawing groups, such as halogens and lower alkyl groups (C_{1-10}) that possibly are substituted with electron withdrawing groups, such as halogens;

c) Z and Y are selected among oxygen, sulphur or nitrogen, with the provision that the nitrogen may carry a positive charge.

Claims 1-8 are directed to the method for enrichment.

Issues

1. Whether claims 1-8 are properly rejected under 35 U.S.C. § 112, first paragraph.

Grouping of Claims

All of the rejected claims in the rejection appealed hereunder stand or fall together.

Arguments

1. Claims 1–8 are not properly rejected under 35 U.S.C. § 112, first paragraph.

The Examiner has rejected claims 1–8 under 35 U.S.C. § 112, first paragraph as "as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention."

Specifically, the Examiner stated, "claims 1-8 are drawn to a method for selectively enriching/removing a serum albumin from a mixture of other compounds by contacting said mixture with a ligand (=X). The said ligand having affinity for and enabling binding of the serum albumin."

The Examine continued, "the instant specification recites 14 ligand structures, see pages 13-14. The instant specification recites 3 test proteins; see page 14, lines 2-4. As best understood, The [the] results of the binding recite that based on conventional ways of interpreting the chromatogram recorded, none of the ligand structures showed binding to IgG or HSA...Further, the instant specification recites that all chromatograms for IgG looked the same and the position of the eluted IgG suggested no interaction/binding (see page 16, lines 9-11)."

The Examiner further continued, "accordingly, based upon the apparent (and confusing) results set forth, e.g., on pages 15-16 of the instant specification with respect to the non-binding of albumin to the disclosed/ claimed ligand structures, the claimed invention is not deemed enabled."

In response, Appellants directed the Examiner's attention to the discussion of the experimental results at 16-17 of the captioned application. The Appellants pointed out that two sets of experiments were run to determine the binding of HSA in PBS at pH of 7 and in West buffer at pH 4.6. As stated in the paragraph bridging pages 16-17, in the West buffer "the chromatograms indicated that all HSA applied and a part of the BSA applied were bound in West pH 4.6 (no HSA was eluted until PBS pH 7 was applied, one portion/peak of BSA eluted with West 4.6 and another with PBS pH 7). Appellants

concluded that it can clearly be seen that albumin is found by all of the recited ligand structures under the appropriate pH condition".

Appellants further continued that for binding at pH 7, which the specification does indeed indicate that using conventional ways of interpreting the chromatograms recorded, none of the ligand structures show binding to IgG or HSA. However, at the top of page 16 (line 5), the application specifically states, "in spite of these negative results the present inventors went further on and analyzed in more detail the shape and position of the peaks of the chromatograms". The remainder of that paragraph and the following paragraph detail that, while IgG was not bound, HSA was bound by seven of the structures.

Appellants concluded that all of recited ligand structures tested will bind HSA under the appropriate conditions, and many will bind even at conditions of neutrality (pH 7). Thus, Appellants respectfully disagree with the Examiner that "the claimed invention is not deemed enabled".

In response, the Examiner stated, "Applicants contends that two sets of experiments were run to determine the binding of HAS in PBS at ph7 and in West buffer at pH 4.6. Applicants contend that albumin is found by al of the recited ligand structures under the appropriate pH conditions. The Examiner contends that the only ligand structure studied with HSA and with BSA was ligand structure 11, see instant specification, page 16, lines 29-30. It is unknown that binding occurred with the other ligand structures, therefore, the other ligand structures are not enabled".

The Examiner continued, "Applicant further contends that in spite of none of the ligand structures showing binding to IgG or HSA using conventional ways of interpreting

the chromatograms recorded, the present inventors went further on and analyzed in more detail the shape and position of the peaks of the chromatograms. The Examiner contends one of the ordinary skilled in the art would have gone to further than the conventional ways of interpreting the chromatograms recorded, therefore, the instant claims are not enabled".

In response, Appellants respectfully dispute the Examiner's contentions. Specifically, as stated on page 16, structures 1-14 were tested for the binding HSA in PBS at pH7, and 7 (3, 4, 6, 8, 9, 12, and 13) showed an HSA peak located at the same elution volume and having the same shape. The other composition (1, 2, 5, 7, 10, 11, and 14) demonstrated an interaction with the media which in apparent from the shoulders and tailing of the peaks. Appellants respectfully assert this demonstrates that such compositions are useful for enriching/removing a serum albumin from a mixture of other compounds, and further, that such analyses of the chromatograms are known and practiced by those skilled in the art.

Likewise, at page 16-17 the results were at ph 4.6 demonstrate binding occurred with ligand structure 11 (the only structure studied at this pH) but the Appellants respectfully submit that structure 11 would be some where of behavioral of other structures in the groups, and as much as binding in pH7 is similar.

Accordingly, Appellants respectfully assert that the instant invention is enabled by the specifications. Further, Appellants respectfully assert that inclusion of working examples is not required, and the only requirement is that the invention be presented in terms which would permit one of the ordinary skilled in the art to practice the claim invention. Appellants respectfully submit that they have done so here, and that one

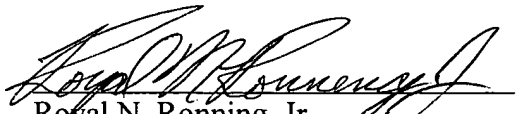
skilled in the art would readily be able to determine which structures will or will not bind the serum albumin and under what conditions.

In view of the foregoing, Appellants respectfully submit that the Examiner's rejection cannot be upheld and should be reversed.

Conclusion

In view of the foregoing arguments, Appellants respectfully assert that the Examiner's rejections presented above cannot be sustained, and should be reversed.

Respectfully submitted,



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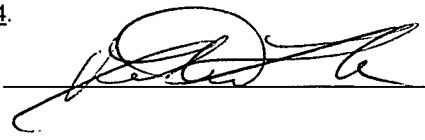
Signature: 

Name: Melissa Leck

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APPENDIX A

The Rejected Claims

Claim 1 (previously presented): In a method for selectively enriching/removing a serum albumin from a mixture of other compounds by contacting said mixture with a ligand (= X), the improvement comprising said ligand

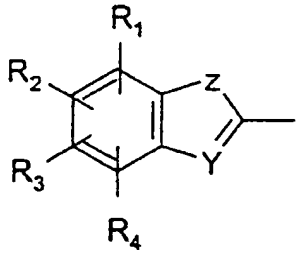
a) having affinity for and enabling binding of the serum albumin and

b) being attached via a spacer (= B) to a base matrix (= M') insoluble in the aqueous media used, the matrix with the attached ligand being represented by

M-B-X

where M is the matrix, B is the spacer and X the affinity ligand, with the provision that M may contain further groups X linked via a spacer,

wherein said ligand X has been selected among serum albumin-binding structures complying with the formulae



in which

a) the free valence bind to the spacer B;

b) R_{1-4} are selected from hydrogen, electron-withdrawing groups, such as halogens and lower alkyl groups (C_{1-10}) that possibly are substituted with electron withdrawing groups, such as halogens;

c) Z and Y are selected among oxygen, sulphur or nitrogen, with the provision that the nitrogen may carry a positive charge.

Claim 2 (previously presented): The method of claim 1, wherein contact between the mixture and the media M-B-X is done in an aqueous media having a pH at which the -B-X carries a positive charge.

Claim 3 (previously presented): The method of claim 1, wherein at least one of R_{1-4} exhibit an electron withdrawing group, preferably selected among halogens such as fluorine.

Claim 4 (previously presented): The method of claim 1, wherein the spacer has a sulphur atom next to X.

Claim 5 (previously presented): The method of claim 1, wherein Z and Y are nitrogens, one of which binding to a hydrogen and the ligand structure being charged depending of pH.

Claim 6 (previously presented): The method of claim 1, wherein said mixture derives from a host in which said serum albumin is human serum albumin.

Claim 7 (previously presented): The method of claim 1, wherein said ligand is attached covalently to said matrix.

Claim 8 (previously presented): The method of claim 1, wherein after the adsorption step said serum albumin is eluted from said affinity adsorbent and if necessary further processed.